IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

TEXAS MEDICAL ASSOCIATION, DR. ADAM CORLEY, TYLER REGIONAL HOSPITAL, LLC, TEXAS RADIOLOGICAL SOCIETY, and HOUSTON RADIOLOGY ASSOCIATED, *Plaintiffs*, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF PERSONNEL MANAGEMENT, DEPARTMENT OF LABOR, DEPARTMENT OF THE TREASURY, CENTERS FOR MEDICARE & MEDICAID SERVICES, XAVIER BECERRA *in his official capacity as the Secretary of Health and Human Services*; KIRAN AHUJA *in her official capacity as the Director of the Office of Personnel Management*, JANET YELLEN *in her official capacity as the Secretary of the Treasury*, MARTIN J. WALSH *in his official capacity as the Secretary of Labor*, and CHIQUITA BROOKS-LASURE *in her official capacity as Administrator of the Centers for Medicare & Medicaid Services*, *Defendants*.	)	Civil Action No. _____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs Texas Medical Association, Dr. Adam Corley, Tyler Regional Hospital, LLC, Texas Radiological Society, and Houston Radiology Associated bring this action for declaratory and injunctive relief against defendants the United States Department of Health and Human Services, Office of Personnel Management, Department of Labor, and Department of the Treasury (collectively, "the Departments"), along with the Centers for Medicare & Medicaid Services ("CMS"), and the current heads of those agencies in their official capacities, and allege as follows:

INTRODUCTION

1. This case challenges yet another set of actions taken by the Departments in violation of their obligations under the No Surprises Act ("NSA") and the Administrative Procedure Act ("APA") to establish a fair and workable independent dispute resolution ("IDR") process that allows out-of-network physicians to obtain reasonable compensation for their services. Congress created the IDR process to ensure that out-of-network healthcare providers could obtain fair and reasonable reimbursement for the medical services they provide, and it specifically declined to impose an amount-in-controversy requirement to access IDR. But the Departments' latest action effectively closes the door to IDR for many out-of-network physicians with small-value claims, threatening the viability of their practices and ultimately placing patient health at risk.

2. Specifically, on December 23, 2022, CMS announced on behalf of the Departments that the nonrefundable administrative fee that each party to an IDR proceeding must pay—win or lose—was being increased *sevenfold*, from $50 to $350. This expense is in addition to the other costs of arbitration, including the arbitrator's fee paid by the losing party. The Departments' dramatic and surprise increase in the cost of accessing IDR—announced less than two months after CMS confirmed that the administrative fee would remain $50 in 2023, and only four business days

before the fee increase took effect—not only will make the process significantly more expensive for all IDR participants but will make it cost-prohibitive for many providers to access IDR at all.

3. If providers are forced to pay a nonrefundable $350 administrative fee just to have their claims heard, insurers—who are permitted under the statute to unilaterally decide how much they pay providers in the first instance—will be able to underpay providers with impunity. Whenever the amount in controversy (*i.e.*, the difference between the amount offered by the insurer and the amount the provider believes it is owed) is $350 or less, it will be economically infeasible for the provider to initiate IDR. Even if the provider won, it would come out behind.

4. While the 600% increase in the administrative fee will harm all out-of-network physicians who rely on IDR to get paid, it will be devastating for those specialties that mostly have small-value claims. Take radiology—almost *all* radiology claims are for less than $350. A nonrefundable $350 fee—simply to initiate the IDR process—thus poses an obvious and acute problem for radiologists' ability to utilize the IDR process to be fairly paid. Consider a real-world example: If a radiologist submits a claim for $199.41 for a computed tomography ("CT") of the abdomen, and the insurer offers to pay only $102.24, what, exactly, is the radiologist supposed to do? Submitting the claim to IDR would be economically irrational because even if the radiologist prevailed, he or she would spend $350 in administrative fees to recover only $97.17, producing a net loss of $252.83—without even considering the provider's internal overhead costs to file the claim. The provider must also consider that it will not prevail on all of its claims and therefore will have to pay the arbitrator's fee, which can now be as high as $938, at least some of the time. Of course, to make arbitration worthwhile, the amount recouped must be greater than the amount spent to bring the claim. The Departments' new nonrefundable $350 administrative fee ensures that arbitration will rarely be worthwhile for radiologists and other similarly situated physicians, effectively

barring them from pursuing IDR to obtain adequate reimbursement for their out-of-network services.

5. In making this sudden and drastic change (posted online two calendar days before Christmas and only four business days before the effective date of January 1, 2023), the Departments did not provide notice or an opportunity for affected parties to comment, as the APA requires. Instead, the Departments set the fee through subregulatory guidance, without giving providers an opportunity to be heard or to explain how a 600% fee increase would prevent them from accessing the NSA's IDR process to obtain reimbursement for their out-of-network services, why the fee increase was unnecessary, and how the Departments could cover their administrative costs without so severely restricting access to IDR. For this reason alone, the fee increase is procedurally invalid and must be set aside.

6. The fee increase is also substantively unlawful because it does not reasonably implement the NSA's IDR process and is arbitrary and capricious. Most glaringly, the Departments entirely failed to consider how their 600% fee increase would impact providers' ability to access IDR—an important aspect of the problem, if ever there was one. Agencies have a fundamental obligation to consider how their actions will affect regulated parties, particularly where, as here, the consequences will be economically crippling and eviscerate a foundational component of the law passed by Congress. Yet the Departments completely ignored how their increased nonrefundable $350 administrative fee would prevent physicians with small-value claims from using the IDR process to obtain fair reimbursement for their services. Similarly, the Departments wholly failed to consider readily available alternatives that would have allowed them to cover their administra-

tive costs without locking providers out of IDR—including by enforcing their own regulation requiring payment of administrative fees at the outset of IDR and by requiring insurers to supply the information providers need to determine whether their claims are IDR-eligible.

7. The Departments cannot cure these problems with their exorbitant new administrative fee by pointing to their regulations authorizing parties to "batch" related claims in certain circumstances. To begin with, the Departments did not advance that rationale when increasing the administrative fee—because they did not address the access problem *at all*. Therefore, they cannot now rely on that *post hoc* justification to defend their unlawful action in court.

8. Moreover, a crucial provision of the Departments' batching rule is itself unlawful because it, too, unduly restricts access to IDR for out-of-network providers with small-value claims that can be effectively vindicated only if joined together in a single proceeding. The Departments' rule permits batching in a significantly narrower range of circumstances than the statute allows: whereas the statute allows the Departments to permit batching if the items and services are "related to the treatment of a similar condition," 42 U.S.C. § 300gg-111(c)(3)(A)(iii), the Departments' rule permits batching only if the items and services are "the same or similar items or services," 45 C.F.R. § 149.510(c)(3)(i)(C), *i.e.*, "if each is billed under the same service code," *id.*

9. Thus, the statute allows the Departments to permit batching of claims for all of the treatments or procedures in a patient's treatment plan, in a patient's episode of care, or even across patients with similar conditions. But the Departments chose instead to restrict batching to claims involving the same service code. The Departments' rule leads to absurd results. Under the same-service-code rule, a single radiology encounter between one radiologist and one patient can lead to a half dozen or more different claims, all of which must be submitted and reviewed separately in IDR, likely by different arbitrators. For example, a patient who arrives at the emergency room

after a serious car crash might receive CT scans of the chest, pelvis, and cervical spine, as well as multiple x-rays. Although each of these necessary and critical radiology services was provided to the same patient on the same day in the same place, *each* CT scan and *each* x-ray must be submitted separately to IDR under the Departments' rule because each corresponds to a different service code.

10. In adopting their service-code-only approach, the Departments did not even *acknowledge* the discrepancy between the statute and their rule, let alone explain why failing to permit batching in all the circumstances where Congress allowed for it would achieve Congress's express efficiency and cost-minimization objectives. Nor did the Departments grapple with how their narrower rule would block access to IDR for providers with small-value claims.

11. The Departments' failure to address these issues is unsurprising given that the batching rule, like the administrative fee increase, was unlawfully issued without notice and comment. The batching rule is part of the same package of rules from September 2021 that included the "rebuttable presumption" in favor of the qualifying payment amount ("QPA"), which this Court has already held was issued in violation of the APA's notice-and-comment requirement. *See Texas Med. Ass'n v. United States Dep't of Health & Hum. Servs.* ("*TMA I*"), 587 F. Supp. 3d 528, 543–48 (E.D. Tex. 2022). For the same reasons that this Court held the Departments lacked good cause for bypassing notice and comment when issuing the QPA rebuttable presumption, the Departments lacked good cause for bypassing notice and comment when issuing their restrictive batching rule.

12. In short, the Departments' new $350 administrative fee and their same-service-code batching rule are both procedurally and substantively unlawful and will be economically devastat-

ing for physicians, like radiologists, who have small-value claims. Individually and in combination, the Departments' actions dramatically curtail access to the IDR process, thus hindering physicians' ability to obtain adequate reimbursement for their services and ultimately placing their economic livelihoods and patient health at risk. The challenged actions should be swiftly vacated, before they inflict further harm on the nation's healthcare providers and the patients they serve.

PARTIES

13. Plaintiff Texas Medical Association ("TMA") is a trade association that represents more than 56,000 physicians and medical students. The nation's largest state medical society, TMA has its headquarters and principal place of business in Austin, Texas. TMA brings this suit on behalf of its healthcare provider members who utilize the NSA's IDR process to obtain reimbursement for their out-of-network services. This lawsuit is consistent with TMA's purpose to resolve challenges its members encounter in caring for their patients, and neither the claim asserted nor the relief requested requires participation of TMA's individual members.

14. Plaintiff Adam Corley is a physician who resides and practices in Tyler, Texas. Dr. Corley works through Precision Emergency Physicians, PLLC, for which he receives hourly reimbursement for providing emergency medical services. Dr. Corley also owns a percentage of a freestanding emergency department in Tyler, Texas, and receives dividends based on profits from the facility. Dr. Corley furnishes out-of-network services that are subject to the NSA's balance-billing provisions and participates in the IDR process to resolve disputes with insurers over appropriate reimbursement rates.

15. Plaintiff Tyler Regional Hospital, LLC d/b/a UT Health East Texas is a hospital in Tyler, Texas, that provides emergency services as defined in the NSA. The Hospital has participated in the NSA's open negotiation process and anticipates participating in the IDR process to resolve disputes with insurers over appropriate reimbursement rates.

16. Plaintiff Texas Radiological Society ("TRS") is a professional medical society comprising more than 2,800 diagnostic radiologists, interventional radiologists, radiation oncologists, medical physicists, residents, and fellows in training throughout the state of Texas. TRS has its headquarters and principal place of business in San Antonio, Texas. TRS brings this suit on behalf of its physician members who utilize the NSA's IDR process to obtain reimbursement for radiology services they furnish on an out-of-network basis. This lawsuit aligns with TRS's objective of serving, promoting, and advancing the profession of radiology in Texas, providing patient-centered care, and removing obstacles to accessing radiology services. Neither the claim asserted nor the relief requested requires participation of TRS's individual members.

17. Plaintiff Houston Radiology Associated ("HRA") is a radiology group practice representing more than 80 radiologists in 17 locations throughout the Houston metropolitan area. HRA is Houston's oldest established radiology group practice and has its headquarters and principal place of business in Houston, Texas. HRA utilizes the NSA's IDR process to obtain reimbursement for the radiology services that HRA radiologists furnish on an out-of-network basis.

18. Defendant Department of Health and Human Services is an executive department of the United States headquartered in Washington, D.C.

19. Defendant Office of Personnel Management is an executive department of the United States headquartered in Washington, D.C.

20. Defendant Department of the Treasury is an executive department of the United States headquartered in Washington, D.C.

21. Defendant Department of Labor is an executive department of the United States headquartered in Washington, D.C.

22. Defendant CMS is an executive agency of the United States headquartered in Washington, D.C.

23. Defendant Xavier Becerra is the Secretary of Health and Human Services. Secretary Becerra is sued in his official capacity only.

24. Defendant Kiran Ahuja is the Director of the Office of Personnel Management. Director Ahuja is sued in her official capacity only.

25. Defendant Janet Yellen is the Secretary of the Treasury. Secretary Yellen is sued in her official capacity only.

26. Defendant Martin J. Walsh is the Secretary of Labor. Secretary Walsh is sued in his official capacity only.

27. Defendant Chiquita Brooks-LaSure is the Administrator of CMS. Administrator Brooks-LaSure is sued in her official capacity only.

JURISDICTION AND VENUE

28. The Court has jurisdiction over this action under 28 U.S.C. § 1331 and the APA, 5 U.S.C. §§ 701–06. Plaintiffs are entitled to the requested declaratory and injunctive relief under the APA and the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02.

29. Venue is proper in this judicial district under 28 U.S.C. § 1391(e) because this is an action against officers and agencies of the United States, at least one plaintiff resides in this district, and no real property is involved in this action.

BACKGROUND

A. The No Surprises Act

30. Traditionally, when a patient with private insurance coverage receives medical care from an "in-network" provider, the insurer pays the provider the rate the insurer and provider had negotiated and agreed to by contract. The patient is responsible for the cost-sharing that is required

by his or her insurance plan, such as a co-pay, coinsurance, and any deductible. If there is a difference between a provider's billed charges and the contracted rate a provider receives from the insurer, the patient is not billed for the difference.

31. If the insurer and provider have not signed an agreement, the provider is "out-of-network." When a patient receives care from an out-of-network provider, the provider submits a bill to the patient's insurer, and the insurer determines how much to pay the provider. In addition to applicable out-of-network cost-sharing, the outstanding balance—the difference between what the provider billed and how much the insurer paid—would be the patient's responsibility. To collect that balance, the provider historically could send the patient a "balance bill."

32. "Balance bills" are sometimes called "surprise bills" because they may result from situations in which patients did not know they had received care from an out-of-network provider, such as in the case of emergency care or care provided at an in-network facility by an independent out-of-network healthcare provider.

33. The NSA addresses these situations.[1] Under the NSA, if a patient has not consented to receive out-of-network care, the patient's cost-sharing responsibility for emergency services furnished by an out-of-network provider, or non-emergency services furnished by an out-of-network provider at an in-network facility, may not exceed the cost-sharing requirement that would

[1] The NSA made parallel amendments to provisions of the Public Health Service ("PHS") Act, which is enforced by the Department of Health and Human Services ("HHS"); the Employee Retirement Income Security Act ("ERISA"), which is enforced by the Department of Labor; and the Internal Revenue Code ("IRC"), which is enforced by the Department of the Treasury. Many of the implementing regulations are parallel provisions that apply, as relevant, to group health plans ("plans") and health insurance issuers offering group or individual health insurance coverage ("issuers") (collectively, "insurers"). The relevant statutory and regulatory provisions appear in triplicate and are identical in all material respects. The NSA's IDR provisions are codified at 42 U.S.C. § 300gg-111 (PHS Act), 29 U.S.C. § 1185e (ERISA), and 26 U.S.C. § 9816 (IRC). For ease of reference, this complaint cites the PHS Act and implementing regulations.

apply if the services had been provided by an in-network provider or facility. 42 U.S.C. § 300gg-111(a)(1)(C)(ii), (b)(1)(A).

34. In these circumstances, the NSA also prohibits out-of-network providers from balance billing the patient for amounts not covered by the patient's insurer. Instead, the NSA requires insurers to pay providers an "out-of-network rate" as defined in the statute, less the patient's cost-sharing requirement. *Id.* § 300gg-111(a)(1)(C)(iv)(II), (b)(1)(D).

B. The IDR Process

35. The NSA sets forth a detailed IDR process for resolving disputes between providers and insurers regarding out-of-network reimbursement rates. *See id*. § 300gg-111(c). If there is no applicable All-Payer Model Agreement and no relevant state law mandating a method to determine the total amount payable to an out-of-network provider, the NSA authorizes insurers to make an initial payment in whatever amount they choose, *id.* § 300gg-111(b)(1), and then channels reimbursement disputes through a carefully designed process of open negotiation, followed, if necessary, by arbitration before an independent arbitrator, referred to as a "certified IDR entity."

36. Specifically, the process begins when the insurer sends the provider the payment the insurer has chosen or a notice of denial of payment. *Id.* § 300gg-111(a)(1)(C)(iv)(I), (a)(3)(K). This begins a statutory period of open negotiation. If the provider disagrees with the insurer's payment, either party may, within four days following the conclusion of the open negotiation period, initiate arbitration through the IDR process. *Id.* § 300gg-111(a)(3)(K), (c)(1)(B).[2]

37. The statute prescribes a "baseball-style" arbitration in which the provider and insurer submit their best and final offers for the amount each considers to be reasonable payment,

[2] The parties may continue their negotiations during the arbitration process. If they reach an agreement on the out-of-network rate before the arbitrator determines an out-of-network rate, their agreed-upon rate controls. 42 U.S.C. § 300gg-111(c)(2)(B).

along with any information requested by the arbitrator and any additional information the party wishes the arbitrator to consider relating to its offer. *Id.* § 300gg-111(c)(5)(B), (C)(ii).

38. The arbitrator must then choose one of the parties' offers after "taking into account" factors specified in the statute. *Id*. § 300gg-111(c)(5)(A)(i). For example, arbitrators "shall consider" the QPA for the item or service, *id*. § 300gg-111(c)(5)(C)(i)(I), which is generally "the median of the contracted rates recognized" by the insurer "for the same or a similar item or service" in 2019, with annual inflation adjustments, *id.* § 300gg-111(a)(3)(E)(i)(I). Arbitrators must also consider information on several "additional circumstances." *Id.* § 300gg-111(c)(5)(C)(ii).

39. Congress took great care in designing this process. It was the product of extensive deliberation and compromise, during which legislators considered a variety of approaches. Multiple proposed bills would have restricted the IDR process to claims for items or services for which the insurer's median in-network rate met or exceeded a threshold amount—in one bill, $1,250, and in another, $750. H.R. 2328, 116th Cong. (2019); H.R. 5800, 116th Cong. (2020); *see also* H.R. Rep. No. 116-615, at 60 (Dec. 2, 2020) ("This section permits providers and payers to elect to utilize the IDR process for any amounts for which the median contracted rate is at least $750."). For claims below those amounts, arbitration would not be available, and payment for out-of-network services would be a set amount, such as the insurer's median contracted rate for similar items or services. *See* H.R. 2328; H.R. Rep. No. 116-615, at 48. But Congress ultimately rejected these options in favor of an arbitration process open to all claims, regardless of their dollar amount.

40. Further, although the statute permits either party to initiate open negotiation or arbitration, in practice, the IDR process primarily protects the economic interests of healthcare providers in receiving fair and adequate reimbursement for their out-of-network services. Congress allowed insurers to unilaterally select the initial payment amount, 42 U.S.C. § 300gg-111(b)(1),

and did not require insurers to offer a larger payment during the open negotiation period, *see id.* § 300gg-111(c)(1)(A). Thus, insurers can protect their interests by simply resting on the status quo they created through their initial payment, without initiating IDR.

41. By contrast, providers who believe an insurer's offer does not represent a reasonable reimbursement rate must resort to IDR to compel payment of the statutory "out-of-network rate" determined by the arbitrator. Unsurprisingly, given this dynamic, in the first five-and-a-half months of the IDR process's existence, providers and healthcare facilities initiated *over 99%* of arbitrations. *See* Dep'ts, *Initial Report on the Independent Dispute Resolution (IDR) Process April 15–September 30, 2022*, at 15–16 (Sept. 30, 2022) ("Initial IDR Report").[3]

C. Aspects of the IDR Process at Issue: Administrative Fees and Batching Criteria

1. IDR Fees

42. To access the IDR process, parties generally must pay two types of fees. The NSA authorizes: (1) certified IDR entity fees that compensate arbitrators and (2) administrative fees that cover government expenses associated with the IDR process more generally. *See* 42 U.S.C. § 300gg-111(c)(5)(F) (certified IDR entity fees); *id.* § 300gg-111(c)(8) (administrative fees).

43. As for the first type of fees (not at issue here), the NSA takes as a given that IDR entities will charge for their services: the statute provides that "the party whose offer is not chosen" by the IDR entity "shall be responsible for paying all fees charged by such entity." *Id.* § 300gg-111(c)(5)(F)(i). In other words, the loser pays the arbitrator's fees. If the parties settle before the IDR entity makes its payment determination, then "each party shall pay half of all fees charged by such entity, unless the parties otherwise agree." *Id.* § 300gg-111(c)(5)(F)(ii). Beyond allocating

[3] https://www.cms.gov/files/document/initial-report-idr-april-15-september-30-2022.pdf.

responsibility for paying these fees, however, the NSA does not specify how much IDR entities may charge or when those fees should be assessed.

44. The NSA also requires that "[e]ach party" pay to the Departments an "[a]dministrative fee" "for participating in the IDR process." *Id.* § 300gg-111(c)(8)(A). The statute authorizes the Departments to determine when and how the parties should pay these fees. *See id*. § 300gg-111(c)(8)(A) (parties must pay "at such time and in such manner as specified by the Secretary"). The Departments must also "establis[h]" the "amount" of the fee each party must pay. *See id.* § 300gg-111(c)(8)(B) (parties must pay "an amount established by the Secretary").

45. Unlike for the IDR entity fees, the NSA does not specify whether the party whose offer is selected should pay a lower administrative fee. But the statute does impose an important condition on the Departments' discretion in setting the amount of the fee. Namely, the Departments must set the administrative fee such that the total amount of administrative fees paid in a given year will cover the estimated costs of running the IDR process for that year. *See id*. § 300gg-111(c)(8)(B) (administrative fees must be set "in a manner such that the total amount of fees paid … for such year is estimated to be equal to the amount of expenditures estimated to be made by the [Departments] for such year in carrying out the IDR process").

2. Batching of IDR Dispute Items and Services

46. The NSA also addresses joinder of related claims. In a provision entitled "[t]reatment of batching of items and services," the statute requires the Departments to "specify criteria under which multiple qualified IDR dispute items and services are permitted to be considered jointly" by an IDR entity "as part of a single determination … for purposes of encouraging the efficiency (including minimizing costs) of the IDR process." *Id.* § 300gg-111(c)(3)(A).

47. Congress further instructed the Departments that the specified criteria should permit items and services to be batched "only if":

i. the items and services are furnished by the same provider or facility, *id.* § 300gg-111(c)(3)(A)(i);

ii. payment for the items and services is required to be made by the same plan or issuer, *id.* § 300gg-111(c)(3)(A)(ii);

iii. the items and services are "related to the treatment of a similar condition," *id.* § 300gg-111(c)(3)(A)(iii); and

iv. the items and services were furnished within the same 30-day period or an "alternative period as determined by the Secretary, for use in limited situations … to encourage procedural efficiency and minimize health plan and provider administrative costs," *id.* § 300gg-111(c)(3)(A)(iv).

48. Thus, to promote "efficiency" and "minimiz[e] costs" of IDR, Congress required the Departments to allow parties to submit multiple claims at once for resolution as part of a single arbitration, if certain conditions are met.

D. The September Rule

49. Congress left certain aspects of the IDR process to be implemented by the Departments, and directed them, "[n]ot later than 1 year after" the NSA's enactment, *i.e.*, by December 27, 2021, to "establish" the IDR process "by regulation." *Id.* § 300gg-111(c)(2)(A).

50. On September 30, 2021, the Departments publicly released the rule at issue here. 86 Fed. Reg. 55,980 (Oct. 7, 2021). The September Rule is an interim final rule, and the Departments issued it without providing notice or an opportunity for interested parties to comment.

51. As relevant here, the September Rule adopted rules for IDR fees, *see id.* at 56,001–02, and "specif[ied] criteria under which multiple qualified IDR items and services may be considered jointly as part of one payment determination (batching)," *id.* at 55,994.

1. IDR Entity Fees and Administrative Fees

52. The September Rule addresses the two types of IDR fees that the NSA authorizes.

53. First, the rule sets forth the process for paying the certified IDR entity fees. In keeping with the statute, the Departments' regulation provides that "the party whose offer … is not selected is responsible for the payment to the certified IDR entity of the predetermined fee charged by the certified IDR entity." 45 C.F.R. § 149.510(d)(1)(i). While only the losing party is ultimately responsible for paying the IDR entity fee, the rule nonetheless provides that both parties must pay the fee "at the time the parties submit their offers." *Id.* § 149.510(d)(1)(ii). Then, after the IDR entity makes its determination, the "fee paid by the prevailing party … will be returned to that party within 30 business days following the date of the certified IDR entity's determination." *Id.* As for the amount of the fee, the Departments stated that "certified IDR entities must set the certified IDR entity fee within a predetermined range (or as otherwise approved by the Departments) specified by the Departments through guidance." 86 Fed. Reg. at 56,001.

54. Second, the September Rule addresses administrative fees, delineating when and how the parties must pay them. 45 C.F.R. § 149.510(d)(2)(i); 86 Fed. Reg. at 56,001–02. As for timing, administrative fees must be paid "at the time the certified IDR entity is selected." 45 C.F.R. § 149.510(d)(2)(i). This requirement contrasts with the rule for IDR entity fees, which, as just noted, must be paid later in the IDR process—*i.e.*, "at the time the parties submit their offers" to the arbitrator. *Id*. § 149.510(d)(1)(ii).

55. Like IDR entity fees, administrative fees must be paid "to the certified IDR entity." *Id*. § 149.510(d)(2)(i). As the rule explains, "[h]aving the certified IDR entity collect both the administrative fee and the certified IDR entity fee will help ensure efficiency by streamlining the process and will facilitate administrative convenience for the parties." 86 Fed. Reg. at 56,001. After receiving the administrative fees, the IDR entity must remit them to the Departments. *Id.*

56. The rule also specifies that the administrative fees are "non-refundable," 45 C.F.R. § 149.510(d)(2)(i), even if "the certified IDR entity determines that the case does not qualify for the Federal IDR process," 86 Fed. Reg. at 56,001. This rule was necessary, the Departments explained, because the administrative fees cover the agencies' expenditures in operating the IDR process and "a large part of [those] expenditures … will come from the initiation of the Federal IDR process." *Id.* Thus, "the Departments will have incurred expenditures in instances … in which the certified IDR entity determines that the case does not qualify for the Federal IDR process, and, thus, it is appropriate that the parties should still be expected to pay the fee" in those instances. *Id.*

57. Finally, as to the "amount" of the administrative fee, the rule largely parrots the statute by requiring that the amount be "established" annually "in a manner such that the total fees paid for a year are estimated to be equal to the projected amount of expenditures by the Departments … for the year in carrying out the Federal IDR process." 45 C.F.R. § 149.510(d)(2)(ii). However, the Departments' regulation goes beyond the statute by purporting to authorize the Departments to set the annual amount of the administrative fee via subregulatory guidance rather than through notice-and-comment rulemaking. *See id.* (providing that "[t]he administrative fee amount will be established *in guidance* published annually" (emphasis added)).

58. The Departments did not offer any justification for authorizing themselves to set the amount of the fee by subregulatory guidance. Instead, the rule simply states that the Departments will take multiple factors into account when assessing "the estimated costs for the Departments to administer the Federal IDR process." 86 Fed. Reg. at 56,001. These considerations include "the staffing and contracting costs related to certifying and providing oversight to certified IDR entities; the costs of developing and publishing reports as required [by the statute]; the costs of collecting the administrative fees from certified IDR entities; and the cost of maintaining the Federal IDR portal." *Id.* at 56,001–02.

2. Batched Items and Services

59. The September Rule also addresses batching.

60. Under the September Rule, "multiple claims … may be submitted and considered jointly as part of one payment determination" by an IDR entity "only if certain conditions are met." *Id*. at 55,994. The Departments set these criteria by reference to the statutory conditions for batching. For each statutory condition, *except* for the Act's requirement that items and services be "related to the treatment of a similar condition," the Departments' rule essentially mirrors the statute.

61. To begin, tracking the statutory condition that batched claims should be claims "furnished by the same provider or facility," 42 U.S.C. § 300gg-111(c)(3)(A)(i), the Departments permitted batching for "items and services … billed by the same provider or group of providers" or the "same facility," as determined by the National Provider Identifier or Tax Identification Number, 45 C.F.R. § 149.510(c)(3)(i)(A).

62. Next, parroting the statutory condition permitting batching only if payment for the items and services is "required to be made by the same group health plan or health insurance issuer," 42 U.S.C. § 300gg-111(c)(3)(A)(ii), the Departments allowed batching only if payment for

the "items and services would be made by the same plan or issuer," 45 C.F.R. § 149.510(c)(3)(i)(B).

63. Further, citing the statutory provision permitting batching only if the items or services were provided within the same 30 business days or "an alternative period as determined by the Secretary, for use in limited situations," 42 U.S.C. § 300gg-111(c)(3)(A)(iv), the Departments permitted batching only where "[a]ll the qualified IDR items and services were furnished within the same 30-business-day period" or, under conditions specified in the September Rule, within "the same 90-calendar-day period," 45 C.F.R. § 149.510(c)(3)(i)(D).

64. Finally, although the corresponding provision of the NSA states that the Departments' criteria may broadly permit batching whenever "items and services are *related to the treatment of a similar condition*," 42 U.S.C. § 300gg-111(c)(3)(A)(iii) (emphasis added), the September Rule authorizes batching only in much narrower circumstances: if the "items and services are *the same or similar items and services*," 45 C.F.R. § 149.510(c)(3)(i)(C) (emphasis added), which the Departments defined as an item or service that is "billed under the same service code, or a comparable code under a different procedural code system," *id.*

65. The Departments adopted this significantly narrower condition so that they could then define "same or similar item or service" to align with the definition of this term as used in the context of QPAs. In an earlier interim final rule from July 2021, the Departments adopted a methodology for how insurers must calculate QPAs, which generally represent the median of the insurer's contracted rates for the same or similar item or service on January 31, 2019, adjusted for inflation. 86 Fed. Reg. at 55,994; *see also* 86 Fed. Reg. 36,872 (July 13, 2021); 45 C.F.R. § 149.140(a)(13). Under that definition, the Departments explained, "same or similar items or services" are "those items and services that are billed under the same service code, or a comparable

code under a different procedural code system." 86 Fed. Reg. at 55,994. The "service codes" include Current Procedural Terminology ("CPT") codes, as well as Healthcare Common Procedure Coding System or Diagnosis-Related Group codes. *Id.*; *see also* 45 C.F.R. § 149.510(c)(3)(i)(C).[4]

66. According to the Departments, batching items and services "involv[ing] the same or similar medical procedure" is "likely to reduce redundant IDR proceedings as well as streamline the certified IDR entity's decision-making." 86 Fed. Reg. at 55,994. The Departments asserted that batching by service code would allow the IDR entity to "more efficiently focus on where the value" of the item or service is "consistently materially different from the QPA" for the relevant item or service, presumably because QPAs too are calculated based on service code. *Id.* at 56,064.

67. At the time of the September Rule, therefore, the Departments acted on the assumption that the relevant QPA would anchor the arbitrator's decisionmaking pursuant to the "rebuttable presumption" the Departments adopted in the same rule. *See id.* at 55,995–97 (explaining that arbitrators were required to select the offer closest to the QPA unless "credible information submitted by the parties clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate"). However, this Court has since invalidated the Departments' "rebuttable presumption" in favor of the QPA. *TMA I*, 587 F. Supp. 3d at 549. In the September Rule, the Departments did not otherwise elaborate on their claim that allowing batching only by service code,

[4] CPT codes assign a unique five-digit code to each healthcare service. *See CPT® Overview and Code Approval*, Am. Med. Ass'n, https://www.ama-assn.org/practice-management/cpt/cpt-overview-and-code-approval (last visited Jan. 17, 2023). Both public and private insurers use CPT codes, which were developed by the American Medical Association, to identify the healthcare services provided and determine whether, and to what extent, the insurer's plan covers a particular service. In other words, CPT codes provide "a uniform language to describe a physician's work, which facilitates patient billing for medical and surgical procedures, diagnostic tests, laboratory studies, and other medical services rendered." *Prompt Med. Sys., L.P. v. Allscriptsmysis Healthcare Sols., Inc.*, 2012 WL 678216, at *1 (E.D. Tex. Feb. 13, 2012). The other types of service codes identified in the Departments' rule serve a similar function.

as opposed to in the full range of circumstances Congress permitted, was "likely to reduce redundan[cy]" and "streamline the certified IDR entity's decision-making." 86 Fed. Reg. at 55,994.

68. In adopting this "same or similar *item or service*" limitation, the Departments never mentioned the statute's language authorizing them to allow batching in a much broader set of circumstances—so long as the claims are "related to the treatment of a similar *condition*." 42 U.S.C. § 300gg-111(c)(3)(A)(iii) (emphasis added). The Departments also did not address whether their approach would prevent batching that is necessary or useful to achieve the "efficiency (including minimizing costs) of the IDR process" that Congress intended. *Id.* § 300gg-111(c)(3)(A). Nor did the Departments consider any alternative to their "same or similar item or service" criterion, or how that criterion would affect access to IDR for out-of-network physicians with small-value claims.

69. Ultimately, the Departments speculated that their restrictive batching criteria could "reduce the per-service cost" of the IDR process by promoting "at least some economies of scale," while acknowledging that they "do not have data or a way to estimate how prevalent batching will be" or the "potential cost savings." 86 Fed. Reg. at 56,054; *see also id.* at 56,064 ("acknowledg[ing] the high degree of uncertainty around" how many claims would be batched under these criteria). On the question of efficiency, the Departments simply asserted that their batching criteria would "avoid combinations of unrelated claims, providers, facilities, … and plans or issuers in a single dispute that could unnecessarily complicate an IDR payment determination and create inefficiencies" in the IDR process. *Id.* at 55,994.

3. The Departments' Rationale for Bypassing Notice and Comment

70. Congress required the Departments to issue regulations establishing the IDR process "[n]ot later than 1 year after December 27, 2020," 42 U.S.C. § 300gg-111(c)(2)(A), the date

the NSA was enacted. Congress thus gave the Departments an entire year to promulgate IDR rules—more than enough time to provide notice and comment and issue a final rule by the statutory deadline. Yet the Departments waited a full nine months to issue the September Rule. And even at that time, there were still three months until the deadline for IDR rules, and five or six months before IDR entities would begin hearing cases. *See* Defs.' Cross-Mot. For Summ. J. and Mem. In Opp. To Pls.' Summ. J. Mots. at 1–2, *TMA I*, No. 6:21-cv-425-JDK, ECF No. 62 (E.D. Tex. Jan. 10, 2022) ("[T]he first arbitrations of payment disputes will likely begin in April [2022].").

71. The Departments nonetheless issued the September Rule without notice and comment. The Departments acknowledged that the APA generally requires notice and comment for legislative rules such as this one. *See* 5 U.S.C. § 553(b)(B); 86 Fed. Reg. at 56,043. They concluded, however, that "good cause" existed for bypassing that requirement. *Id.*

72. The Departments conceded that the full year between the NSA's enactment (on December 27, 2020) and its effective date (January 1, 2022) "may have allowed for the regulations" to be finalized through notice-and-comment rulemaking before the NSA took effect. *Id.* But the Departments asserted that it was "impracticable and contrary to the public interest to engage in full notice and comment rulemaking" before finalizing the September Rule because "this timeframe would not provide sufficient time for the regulated entities to implement the requirements" relating to the IDR process. *Id.* at 56,044.

73. Specifically, the Departments asserted that without the September Rule's regulations for initiating the IDR process and providing information to the IDR entity, providers "will not be able to resort to the Federal IDR process …, leaving the possibility that they will be undercompensated for their services." *Id.* And the Departments further asserted that insurers would need to take into account the IDR regulations as they finalized benefit designs, rates, and plan offerings,

and that IDR entities would need time to apply for certification and be prepared to conduct payment determinations after the Act took effect. *Id.*

74. However, the Departments did not state that it would have been impossible to provide notice and comment and finalize the IDR regulations by the Act's effective date. Nor did they explain why—contrary to Congress's judgment as reflected in the statutory deadline of December 27, 2021, for rules establishing the IDR process—rules regarding batching and administrative fees issued by that date would not give parties and IDR entities sufficient time to be ready to begin conducting arbitrations on schedule in March or April 2022. And they did not specifically address the fee or batching provisions of the rule or explain why it would have been impracticable or contrary to the public interest to provide notice and comment before adopting those provisions.

75. In *TMA I*, this Court held that the Departments had "fail[ed] to comply with the notice-and-comment requirement" in adopting the September Rule's QPA presumption. 587 F. Supp. 3d at 548. The Court first rejected the Departments' contention that they had authority to bypass notice and comment under their organic statutes. *See id.* at 544 (citing cases holding the same). The Court then held that good cause for bypassing notice and comment did not exist, emphasizing that the Departments had "fail[ed] to justify why they could not have provided notice and comment in the time they had—a full year," *id.* at 545, and that the "desire to provide immediate guidance" to regulated parties "without more, does not suffice for good cause," *id.* at 546 (quoting *United States v. Johnson*, 632 F.3d 912, 929 (5th Cir. 2011)). The Court further held that even if good cause existed for *some* of the IDR rules established in the September Rule, such as the rules for certifying IDR entities, "good cause [did] not exist to rush the provisions" establishing the QPA presumption. *Id.* (citing *United States v. Garner*, 767 F.2d 104, 120 (5th Cir. 1985)).

E. September 2021 Fee Guidance

76. On the same day that the Departments issued the September Rule, CMS issued a guidance document relating to the IDR entity fees and administrative fees applicable in 2022. *See Calendar Year 2022 Fee Guidance for the Federal Independent Dispute Resolution Process Under the No Surprises Act* (Sept. 30, 2021) ("September 2021 Fee Guidance").[5] This document set the permissible range of IDR entity fees and established the administrative fee parties would be required to pay during the 2022 calendar year. *Id.*

77. As to the IDR entity fees, CMS announced that IDR entities would be required to "charge a fixed … fee for single determinations within the range of $200–$500" and "$268–$670" for "batched determinations." *Id.* at 4; *see infra* ¶ 90 (discussing subsequent 40% increases to the maximum IDR entity fees for 2023). In setting the permissible range of IDR entity fees, the Departments considered a number of factors, including the input of "stakeholders," who emphasized the importance of ensuring that the IDR entity fees would not make "participating in the Federal IDR process … cost-prohibitive, especially for smaller providers and facilities." *Id.* at 3.

78. As to administrative fees, CMS announced that the administrative fee year for 2022 would be "$50." *Id.* The guidance reaffirmed the September Rule's requirement that "each party to an IDR payment determination … must pay an administrative fee for participating in the Federal IDR process at the time the certified IDR entity is selected." *Id.* at 1. And it specified that the $50 fee would be "due from each party for participating in the [IDR] process," regardless of which party prevailed. *Id.* at 3. The fee amount, the guidance explained, was based on "review of anticipated expenditures by the Departments in carrying out the Federal IDR process for 2022." *Id.*

[5] https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Technical-Guidance-CY2022-Fee-Guidance-Federal-Independent-Dispute-Resolution-Process-NSA.pdf.

F. The IDR Process's Implementation and Backlog

79. On April 15, 2022, the Departments opened the Federal IDR portal, and parties began initiating IDR to adjudicate payment disputes. *See* Initial IDR Report at 3, 7. From the get-go, the volume of IDR submissions was higher than the Departments had anticipated. *Id.* at 7. The Departments had estimated that just over 22,000 claims would be submitted for IDR each year. *See Supporting Statement For Paperwork Reduction Act 1995: Independent Dispute Resolution Process* at 16.[6] As it turned out, over 18,000 claims were submitted by June 30, 2022—just two-and-a-half months into the program. *See* Initial IDR Report at 8. Over the next three months, the number of claims ballooned even further—almost 72,000 claims were submitted between July 1 and September 30. *Id.* at 7.

80. The Departments have yet to offer a reason for the higher-than-expected number of IDR submissions. One possible explanation is that more claims should have been resolved through open negotiation but were not because insurers have largely refused to come to the table, instead resting on their initial payments, which typically track the QPA. The Departments' repeated attempts to make the IDR process QPA-centric have certainly exacerbated this dynamic (and likely contributed to the high volume of disputes more generally) by empowering insurers to lowball providers with payment offers they cannot accept. The high volume of disputes may also be due in part to the incentive the Departments' QPA-centric rules create for insurers to terminate in-network contracts and force more providers out-of-network, a practice that began in earnest almost immediately following the publication of the September Rule. Another contributing factor may be that the Departments' restrictive same-service-code batching rule has required parties to file multiple claims that otherwise could (and should) have been consolidated into a single proceeding.

[6] https://www.dol.gov/sites/dolgov/files/ebsa/laws-and-regulations/laws/no-surprises-act/surprise-billing-part-ii-information-collection-documents-attachment-1.pdf.

81. In any event, as the volume of claims increased over the first six months of the IDR process, the IDR entities did not keep pace with the unexpectedly high volume. In fact, through September 30, only about 23,000 disputes had been closed, creating a massive dispute backlog. Initial IDR Report at 8. Both the NSA and the Departments' regulations require IDR entities to issue payment determinations within 30 business days of their selection. *See* 42 U.S.C. § 300gg-111(c)(5)(A); 45 C.F.R. § 149.510(c)(4)(ii). But the Departments made no attempt to enforce these deadlines as the number of pending disputes continued to mount.

82. The Departments concluded that the "primary cause" for these delays and backlog was not the volume of claims, however, but rather "the complexity of determining whether disputes [were] eligible for the Federal IDR process" at all. Initial IDR Report at 8–9. Many of the claims parties had submitted for IDR were found to be ineligible. IDR entities actually made payment determinations in only 15% of the disputes closed by September 30, 2022, whereas 69% of the cases closed by that date were found ineligible for IDR. *Id.* at 8. In fact, nearly half of all claims submitted for IDR between April 15 and September 30 were challenged by the non-initiating parties on eligibility grounds, with the vast majority of these disputes still pending when the Departments issued their Initial Report to recap the program's first six months. *Id.* at 9.

83. A claim's eligibility for IDR can turn on multiple factors, including whether the claim is subject to a state surprise medical billing law, whether claims were correctly batched, and whether the initiating party met relevant deadlines. *Id.* The Departments' Initial IDR Report identified certain issues that have complicated IDR entities' eligibility determinations. *See id.* at 8–12.

84. To begin with, eligibility determinations have been frustrated by the parties' failure to provide necessary information that insurers are required to disclose to providers "when they make an initial payment or provide a notice of denial of payment," such as the applicable QPA

and contact information. *Id.* at 9. The insurers' failure to comply with their disclosure obligations meant that "many disputes were initiated with missing or incorrect contact information for the non-initiating party" or "missing QPAs." *Id.* And this required "further outreach by certified IDR entities" to gather the requisite information. *Id.* The Departments sought to address this issue by providing insurers with "checklist[s]" to remind them of their disclosure obligations. *Id.*

85. Eligibility determinations have also been complicated by the difficulty of determining whether claims are subject to a state law rather than the Federal IDR process. *See id.* at 10. Here again, though, the lack of adequate disclosures was a root cause of the problem: "[t]he health plan type is nearly always required to determine whether the payment dispute is subject to state law or the Federal IDR process," but "the health plan type"—information insurers possess—"was unknown upon dispute initiation in more than half of disputes initiated from April 15–September 30." *Id.* at 10–11. The need for IDR entities to engage in "additional outreach" to confirm the type of health plan at issue "further delay[ed] the eligibility review process." *Id.* at 11.

86. Lastly, "many disputes were incorrectly batched," which likewise "result[ed] in delays in processing" disputes. *Id.* These problems, too, could have been ameliorated by adequate disclosure by insurers of "[i]nformation about health plan type," which "helps initiating parties accurately batch items or services together." *Id.*

87. Recognizing that the insurers' failure to comply with their disclosure obligations was a significant factor driving the backlog, providers encouraged the Departments to enforce compliance with insurers' existing disclosure obligations and to require further disclosures. Several provider groups, for example, requested that that the Departments require insurers to use uniform remittance advice remark codes in their initial payments, which would "clearly delineate whether every claim is eligible for the Federal IDR process." *See* Letter from the American College

of Emergency Physicians, et al., *Request to Require the Use of Remittance Advice Remark Codes (RARCs)* at 2–3 (Nov. 28, 2022) (explaining that use of these codes would give providers, among other things, "the information they need to know for certain whether state or federal rules apply").[7] Thus far, the Departments have failed to respond to these requests.

88. The morass of eligibility disputes and the IDR backlog have had a significantly adverse financial impact on providers. Many providers participating in IDR have yet to be paid for the vast majority of their services in dispute. Nonetheless, they have had to pay their administrative fees and front the IDR entity fees when they submit their offers. The backlog has meant that providers must then wait many months before they can recover the fronted fees and obtain fair reimbursement for their services. During those months, of course, insurers retain whatever sum the provider is owed. And the Departments have authorized IDR entities to collect interest on the parties' IDR entity fees while disputes are pending. *See* 86 Fed. Reg. at 56,001 ("The certified IDR entity may (but is not required to) accrue interest on the funds. The certified IDR entity is not required to remit any accrued interest to any other party."). So, the longer the delay, the more value providers forfeit.

G. October 2022 Fee Guidance

89. A month after the Departments issued their Initial IDR Report detailing this backlog, CMS posted additional guidance setting the IDR fees for calendar year 2023. *See Calendar Year 2023 Fee Guidance for the Federal Independent Dispute Resolution Process Under the No Surprises Act* (Oct. 31, 2022) ("October 2022 Fee Guidance").[8]

[7] https://www.acep.org/globalassets/new-pdfs/advocacy/acep-edpma-rarc-code-request.pdf.
[8] https://www.cms.gov/cciio/resources/regulations-and-guidance/downloads/cy2023-fee-guidance-federal-independent-dispute-resolution-process-nsa.pdf.

90. The October 2022 Fee Guidance raised the permitted range for IDR entity fees by 40%, to "$200–$700" for single determinations and "$268–$938" for batched determinations. *Id.* at 6. As before, the Departments considered stakeholder interests and the need to prevent the IDR process from becoming "cost-prohibitive, especially for smaller providers and facilities." *Id.* at 5. They nonetheless concluded that an increase in the range for IDR entity fees was necessary because "IDR entities are now processing significantly more disputes than originally anticipated and investing far more effort than expected to determine the eligibility of those disputes." *Id.* at 5.

91. In particular, the guidance emphasized that IDR entities had "expend[ed] considerable time and resources" on eligibility disputes, with over 22,000 disputes having been found ineligible as of September 30, 2022. *Id.* However, "[w]hile the process for eligibility determination informs the overall rate that certified IDR entities are permitted to charge, certified IDR entities may not collect fees for those cases that they ultimately determine are ineligible for the Federal IDR process." *Id.* As a result, "IDR entities are only receiving payment for a small percentage of the disputes as to which they are devoting significant time and resources." *Id.* at 5–6.

92. With respect to administrative fees, the October 2022 Fee Guidance left the $50 fee in place. *Id.* at 4. The guidance stated that the Departments considered the relevant factors regarding the costs of carrying out the IDR process and concluded that existing data did not require a change to the $50 fee for 2023. *See id.* at 3–4. Significantly, however, the guidance stated that parties could wait to pay the administrative fee until "the time of offer submission" rather than when the IDR entity is selected. *Id.* at 1–2. To justify this departure from the September Rule's requirement that the parties must pay the administrative fee when the IDR entity is selected, the October 2022 Fee Guidance pointed to a previous guidance document the Departments had issued to clarify the IDR process for disputing parties. *See id.* at 2 n.4 (citing *Federal Independent Dispute*

Resolution (IDR) Process Guidance for Disputing Parties (October 2022)[9]). This guidance provided that "[a]dministrative fees may be invoiced by the certified IDR entity at the time of selection and must be paid by the time of offer submission." *Process Guidance for Disputing Parties* at 29; *see also id.* at 18, 20. The upshot of this more permissive approach was that the IDR entity would not be required to collect the fee—and the parties would not be required to pay it—until after the IDR entity "concludes that the Federal IDR Process applies." *Id.* at 18; *see also* Dep'ts, *Federal IDR Portal Reference Guide for Certified IDR Entities* at 19 (December 2022) ("After determining that … the dispute is eligible for the Federal IDR process, certified IDR entities are responsible for requesting both parties pay the Administrative and the Certified IDR Entity Fees.").[10]

H. December 2022 Fee Guidance

93. On December 23, 2022, less than two months after issuing the October 2022 Fee Guidance, CMS announced that the Departments had adopted an "Amendment" to the guidance, making no change to the IDR entity fees but "increas[ing] the administrative fee … from $50 to $350 per party … beginning January 1, 2023." *Amendment to the Calendar Year 2023 Fee Guidance for the Federal Independent Dispute Resolution Process under the No Surprises Act: Change in Administrative Fee* at 1 (Dec. 23, 2023) ("December 2022 Fee Guidance").[11]

94. To explain this sudden, sevenfold increase in the nonrefundable administrative fee, the December 2022 Fee Guidance pointed to the problems outlined in the Initial IDR Report—*i.e.*, the higher-than-expected volume of disputes as well as the substantial number of those disputes ultimately determined to be ineligible for the IDR process. *Id.* at 4–5 ("This case load is nearly ten

[9] https://www.cms.gov/files/document/federal-independent-dispute-resolution-guidance-disputing-parties.pdf.
[10] https://regtap.cms.gov/uploads/library/IDR-Tool9FederalIDRPortalReferenceGuide-5CR-011123.pdf.
[11] https://www.cms.gov/cciio/resources/regulations-and-guidance/downloads/amended-cy2023-fee-guidance-federal-independent-dispute-resolution-process-nsa.pdf.

times greater than the Departments initially estimated it would be" with many disputes "involv[ing] complex eligibility determinations"). "This situation," the guidance stated, "has resulted in low collections of the administrative fee relative to the volume of disputes processed in the portal, and … low collections of the administrative fee relative to the Departments' expenditures in the first two calendar quarters of Federal IDR process operations." *Id.* at 5. The Departments failed to note how many of their own decisions have contributed to the high volume of disputes. *See supra* ¶ 80 (discussing how insurers' low initial payments, the Departments' QPA-centric IDR rules, and their restrictive batching rule contribute to the large number of disputes).

95. Of course, an increase in the volume of IDR disputes would ordinarily mean a corresponding increase in administrative fees collected—and if those fees were paid at the outset (as the September Rule prescribes), eligibility determinations would not affect collection. The December 2022 Fee Guidance explains that the reason for the low collection is that "the Departments permit parties to pay the administrative fee on or before the time of offer submission." *Id.* at 5 n.22; *see also id.* at 2 ("[T]he parties must pay the administrative fee by the time of offer submission."). As a result, "[i]f an offer is not submitted because the certified IDR entity determines the dispute is ineligible for the Federal IDR process, the administrative fee is often not collected." *Id.* at 5 n.22. Remarkably, while attributing the collection problem to the timing of payment, the December 2022 Fee Guidance nowhere mentions the Departments' own regulation requiring the parties to "pay" the administrative fee "at the time the certified IDR entity is selected." 45 C.F.R. § 149.510(d)(2)(i).

96. In addition to the low volume of fee collection relative to the high volume of initiated IDR disputes, the December 2022 Fee Guidance also highlights that the Departments "have

engaged government staff and contractor resources to conduct pre-eligibility reviews by performing research and outreach on disputes pending eligibility determinations." December 2022 Fee Guidance at 5. These actions were expected to "expedite the resolution of initiated disputes" by addressing the backlog of eligibility disputes but would also "increas[e] expenditures." *Id.* at 5–6. And the sevenfold fee increase was intended to "reflect" the Departments' "estimated increased expenditures." *Id.* at 6.

97. The December 2022 Fee Guidance does not, however, disclose the data or methodology the Departments used to generate their estimated expenditures and justify the fee increase. The guidance does not disclose the Departments' total estimated expenditures for the year; nor does it disclose the estimated number of disputes in which administrative fees will be collected. The Departments also omitted any estimates regarding how the rate of eligibility disputes (and ineligibility determinations), which had driven the Departments' increased expenditures, might change as insurers improved their compliance with applicable disclosure requirements. This omission is notable, as it appears there has recently been a substantial drop-off in the rate of ineligible disputes. *Compare* October 2022 Fee Guidance at 5 (over 22,000 disputes found ineligible between April 15 and September 30), *with* December 2022 Fee Guidance at 4–5 (only an additional 1,000 disputes found ineligible between September 30 and December 5). Nevertheless, the December 2022 Fee Guidance simply states that the Departments had worked "to make systemic improvements to allow the aggregation of data needed to estimate the rate at which disputes are determined eligible … and the rate at which one or both parties pay the administrative fee." *Id.* at 5. The $50 fee was found insufficient "[a]s a result" of these efforts. *Id.* at 5.

98. The December 2022 Fee Guidance nowhere suggests that the Departments considered that a sevenfold increase in the nonrefundable administrative fee could render the IDR process

cost-prohibitive for many providers, leading them to abandon claims they would otherwise pursue in IDR. This is notable, in part because elsewhere the guidance emphasizes, with regard to IDR entity fees, that the Departments "recogniz[ed] the need to keep the Federal IDR process from being cost-prohibitive for disputing parties." *Id.* at 6.

99. Nor does the December 2022 Fee Guidance suggest the Departments considered any alternatives to their massive fee increase—or any alternatives to their costly efforts to conduct pre-eligibility reviews that purportedly necessitated the fee increase. For instance, despite justifying the fee increase based on the low rate of fee collection from disputes ultimately determined ineligible—and despite acknowledging that the low collection rate was due to failure to collect the administrative fee until after the dispute is determined to be eligible and the offers are submitted—the Departments nowhere considered addressing the collection problem by enforcing their regulation as written and requiring parties to pay the administrative fees at the outset.

100. Similarly, the Departments nowhere considered any alternatives to reduce the number of ineligible disputes submitted to IDR, for example by requiring insurers to use remittance advice remark codes when providing the required disclosures with their initial payment or notice of denial of payment—as stakeholders had previously urged them to do in order to reduce the number of eligibility disputes. *See supra* ¶ 87.

101. The Departments likewise failed to consider the option of allocating the amount of fees differently. For example, given that insurers' failure to comply with their disclosure obligations had significantly contributed to the backlog and additional expenditures in the first place, the Departments could have imposed a $700 administrative fee on insurers whenever they failed to furnish providers with the information necessary to accurately make eligibility determinations.

I. The Adverse Impact on Access to IDR

102. The 600% increase in the administrative fee announced in the December 2022 Fee Guidance will make the IDR process significantly more expensive for all IDR participants. But it is providers, not insurers, who rely on IDR to get paid and who therefore initiate 99% of arbitrations. *See supra* ¶ 41. And for many physicians, like radiologists, whose claims rarely exceed $350, the requirement to pay a nonrefundable $350 administrative fee will make participation in the IDR process cost-prohibitive for the vast majority of their claims.

103. Because insurers are permitted under the statute to unilaterally choose how much they reimburse providers in the first instance, the onus is on providers—who are often dissatisfied with insurers' below-market initial payments—to initiate IDR.[12] When providers furnish services subject to the NSA's balance-billing provisions, insurers often offer an initial payment for those services in an amount equal to the QPA (as unilaterally calculated by the insurer). And QPAs are generally significantly lower than what insurers had historically paid for the same services.

104. Because insurers' initial payments are often less than the amount providers believe they are owed, providers are forced to initiate the open negotiation process. During the negotiations, providers often request a reimbursement rate that is approximately equal to the rate insurers were paying for the provider's services prior to the NSA. But insurers often refuse to negotiate, and rarely budge above the QPA. Even after a physician wins a case, insurers persist in offering lower amounts because arbitrators' rulings are not precedential, forcing providers to repeatedly resort to IDR, and incur all the attendant costs, just to get paid a reasonable amount.

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[12] *See, e.g.*, Corley Decl. at ¶ 11, *Texas Med. Ass'n v. United States Dep't of Health & Hum. Servs.* ("*TMA II*"), ECF No. 41-2 (E.D. Tex. Nov. 12. 2022) (explaining that "Open Negotiation has rarely resulted in out-of-network insurers offering reasonable reimbursement rates," which requires providers "to use IDR to attempt to obtain a reasonable reimbursement rate"); Ford Decl. at ¶¶ 8–11, *TMA II*, ECF No. 41-3 (E.D. Tex. Nov. 12. 2022) (same).

105. But before the fee increase, so long as the amount in controversy—*i.e.*, the difference between the amount offered by the insurer in negotiation and the amount the provider believes it is owed—was more than $50, a provider could typically justify initiating IDR (taking into account, of course, such things as time and effort expended to submit and arbitrate the claim and the possibility of paying the IDR entity fee if the arbitrator selects the insurer's offer).

106. The Departments' fee increase radically changes the economic calculus and prices out many more claims. After the December 2022 Fee Guidance, it will rarely make economic sense to initiate IDR unless the amount in controversy materially exceeds $350.

107. Many claims have a lower amount in controversy. This is especially true for physicians in specialties like radiology that have large numbers of small-value claims. In 2022, over 99% of plaintiff HRA's NSA-eligible charges had an allowed amount of less than $350.[13] Similarly, more than 99% of out-of-network radiology charges in 2022 from a sample of over 100 practices across Texas had an allowed amount of less than $350. To pick just one example: in 2022, the average allowed amount by commercial insurers for an out-of-network mammogram performed by this sample of Texas providers was approximately $32 (down from approximately $63 in 2021). Obviously, a nonrefundable $350 administrative fee would make IDR cost-prohibitive for such claims. Thus, the Departments' new $350 administrative fee effectively closes the door to IDR for radiologists and leaves them forced to accept, in the above example, a 49% reduction in the previous reimbursement rate for performing a life-saving cancer screening. No wonder insurers are motivated to and are in practice taking steps to terminate longstanding market-rate

[13] The "allowed amount" is the amount the insurer determines it will pay to out-of-network providers for a particular item or service. *See N. Cypress Med. Ctr. Operating Co., Ltd. v. Aetna Life Ins. Co.*, 898 F.3d 461, 469 (5th Cir. 2018).

contracts for providers who, as insurers fully understand, will have difficulty obtaining redress for these substantial underpayments through the Departments' flawed IDR process.

108. Batching does not solve the problem. Even assuming the radiologist in the above example could join 10 mammograms together in a single IDR proceeding, the amount in controversy would still likely be less than $350. Thus, absent the ability to broadly batch claims, the Departments' new $350 administrative fee effectively closes the door to IDR for radiologists. Yet the Departments have adopted a restrictive batching rule under which claims may be batched only if they are furnished by the same provider or facility for the same insurer in a relatively short time period and—as relevant here—are billed under the same service code. This will prevent many providers, especially those with small-value claims, from batching a sufficient number of claims to bring the amount in controversy for the dispute above $350.

109. Radiology is again a case in point. A radiology practice could bill for services under approximately 2,000 different CPT codes. In a single day, a radiologist often performs dozens of different procedures, all related to the treatment of similar conditions, but each corresponding to a different service code. Indeed, during a single patient encounter, a radiologist will often furnish multiple items or services that are all related to the treatment of the patient's condition but involve multiple CPT codes—sometimes as many as a half a dozen or more.

110. For example, a football player who suffers upper-body injuries on the field might require CT scans of his head, neck, back, and abdomen, as well as shoulder x-rays and multiple different x-rays of the chest. Because each CT scan and x-ray would be billed to a different CPT code, none of the claims could be batched under the Departments' same-service-code rule. The same would be true for a radiologist's encounter with a child who falls on the playground and injures his or her arm, requiring x-rays of the hand, wrist, forearm, elbow, humerus, and shoulder.

Because each x-ray corresponds to a different CPT code, the radiologist could not batch these claims together into one IDR dispute. And if a radiologist treated multiple patients who suffered falls in a 30-day period, the provider could not batch all of the claims together under the Department's rule, even though the Departments could have made them eligible for batching consistent with the statute because they all relate to the treatment of a similar condition.

111. In combination, the Departments' nonrefundable $350 fee and their restrictive same-service-code rule will drastically curtail the number of charges that physicians, and especially radiologists, can feasibly submit to IDR. Even a large radiology practice that employs over 100 physicians and performs a high volume of IDR-eligible services will find it cost-prohibitive to initiate IDR for the *vast majority* of its claims. For example, as a result of the nonrefundable $350 fee and the service-code restriction on batching, it will be financially infeasible for a large radiology practice in Texas to pursue IDR for a shocking *92%* of its charges.

112. Accordingly, the predictable result of the challenged actions will be to dramatically limit access to the IDR process, and potentially fully shut out certain providers, with devastating consequences for their practices and the patients they serve.

COUNT I

THE DEFENDANTS UNLAWFULLY ISSUED THE CHALLENGED PROVISIONS OF THE SEPTEMBER RULE AND THE DECEMBER 2022 FEE GUIDANCE WITHOUT THE NOTICE AND COMMENT REQUIRED BY THE APA (5 U.S.C. §§ 553, 706)

113. The foregoing paragraphs are incorporated by reference.

114. The December 2022 Fee Guidance violated the APA's procedural requirements because its imposition of a nonrefundable $350 administrative fee for accessing IDR constitutes a substantive rule that did not undergo the requisite notice-and-comment rulemaking.

115. Under the APA, before issuing substantive rules, an agency must generally publish a "notice of proposed rule making," 5 U.S.C. § 553(b), and "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments," *id.* § 553(c). Although the APA exempts certain agency actions, including "interpretative rules" and "rules of agency organization, procedure, or practice," from this requirement, *id.* § 553(b)(A), these exceptions are construed narrowly, and they do not apply to *substantive* rules.

116. The December 2022 Fee Guidance's imposition of a nonrefundable $350 administrative fee as a condition of accessing the IDR process was a substantive rule. The guidance imposed a substantial financial obligation that out-of-network providers must pay in order to submit claims for reimbursement for their services. Absent the December 2022 Fee Guidance, the Departments would have no legal basis for requiring parties to pay the $350 fee.

117. Nothing in the NSA exempts the Departments' duty to "establis[h]" the "amount" of administrative fees, *see* 42 U.S.C. § 300gg-111(c)(8)(B), from Congress's mandate that the Departments "establish" the IDR process "by *regulation*," *id.* § 300gg-111(c)(2)(A) (emphasis added). And nothing in the NSA overrides the APA's procedural requirements or suggests that they do not apply to the establishment of the administrative fee for accessing IDR.

118. Nor could the December 2022 Fee Guidance qualify as an exempt "interpretative" rule. In setting the $350 fee, the Departments did not interpret or clarify any provision of the NSA or the implementing regulations. The guidance did not purport to offer the Departments' view on the meaning of any ambiguous term. Instead, it effected a dramatic change in the payment obligation parties must satisfy to access the IDR process. The December 2022 Fee Guidance thus imposed a new substantive rule—it was not interpretive in any meaningful sense.

119. It is likewise impossible to characterize the Departments' sevenfold fee increase as simply a "rul[e] of agency organization, procedure, or practice." *Id.* § 553(b)(A). The December 2022 Fee Guidance did not establish any internal *agency* procedures or practices. Rather, it imposed a condition for accessing a *private* arbitration process external to the agencies. Virtually every rule the Departments have promulgated regarding the IDR process is "procedural" in some sense: the NSA instructs the Departments to "establish by regulation one independent dispute resolution *process*." 42 U.S.C. § 300gg-111(c)(2)(A) (emphasis added). But that does not exempt all IDR rulemaking under the NSA from the APA's notice-and-comment requirement.

120. Here, moreover, the Departments' 600% increase in the nonrefundable administrative fee materially affects out-of-network providers' ability to vindicate their rights and interests under the NSA—an impact far too substantial for the December 2022 Fee Guidance to be considered procedural, rather than substantive. The sheer magnitude of the fee increase effectively locks many providers out of IDR, by making it cost-prohibitive for virtually all of their claims. And even for those providers not wholly excluded from the IDR process, the fee increase will materially limit the scope and volume of claims they can submit for arbitration.

121. In imposing such a dramatic fee increase—and determining that both insurers and providers must bear that increase evenly, without regard to which party prevails in the dispute or has contributed more to the backlog and additional expenditures—the Departments have made multiple substantive policy judgments. *See, e.g.*, *infra* ¶¶ 141–45 (highlighting alternative actions the Departments might have taken). Such substantive judgments are precisely the sort of decisions that must be subject to the APA's notice-and-comment requirement, which exists to ensure that before an agency takes action materially affecting regulated parties' rights and interests, it gives them notice and an opportunity to be heard. By imposing a sevenfold increase in the nonrefundable

administrative fee without taking into account the input and interests of regulated parties, the Departments repudiated fundamental principles of administrative law and procedure.

122. The Departments cannot justify their failure to provide notice and comment before issuing the December 2022 Fee Guidance by recourse to the September Rule, which purported to authorize the Departments to set fees through guidance. Because these fee rules are substantive, the APA requires that they go through notice and comment. The Departments cannot promulgate a rule authorizing themselves to violate the APA by issuing substantive rules via guidance.

123. There is, moreover, an independent reason why the September Rule cannot justify the December 2022 Fee Guidance: the September Rule's administrative fee and batching regulations were themselves issued without notice and comment in violation of the APA.

124. The Departments claimed that there was "good cause" to bypass that requirement for the September Rule because providing notice and comment was purportedly "impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(B).

125. Because the notice-and-comment requirement is a bedrock procedural protection designed to ensure that members of the public have notice of proposed regulations that might affect their interests and an opportunity to present their views to the agency, the "good cause" exception is construed narrowly and is reserved for emergency situations in which delay would cause serious harm and interfere with the agency's ability to carry out its statutory mandate. The APA's notice-and-comment provision reflects Congress's judgment that it is almost always in the public interest to provide notice and comment before taking action that impairs parties' rights and interests.

126. This case is no exception. Contrary to the Departments' claim that it was in the "public interest" to bypass notice and comment in promulgating the September Rule, 86 Fed. Reg. at 56,043, the Departments' failure to provide notice and comment led them to take actions harmful

to the public interest, including dramatically curtailing access to the IDR process and thereby compromising physicians' ability to obtain redress when insurers underpay them. Indeed, the Departments themselves recognized that "undercompensation could threaten the viability of … providers," which "in turn, could lead to participants, beneficiaries and enrollees not receiving needed medical care, undermining the goals of the No Surprises Act." *Id.* at 56,044.

127. For the same reasons this Court held in *TMA I* that the Departments lacked good cause for issuing the QPA presumption without notice and comment, *see* 587 F. Supp. 3d at 545–46, the Departments cannot satisfy the high bar necessary to establish good cause for issuing the administrative fee and batching rules without notice and comment.

128. Congress gave the Departments an entire year to promulgate IDR regulations—more than sufficient time to formulate proposed rules and provide notice and opportunity for comment. Yet the Departments waited a full nine months to act. The Departments cannot, through their own nine-month delay, create an exigency justifying dispensing with notice and comment.

129. Even in late September 2021, there was no exigency that could justify issuing the administrative fee and batching regulations without notice and comment. At that time, there remained three months until the NSA took effect, and five or six months until the first arbitrations would begin in March or April 2022. There was still enough time to provide notice and comment.

130. Nor can the Departments justify omitting notice and comment by claiming that regulated parties needed lead time. In setting the December 27, 2021 deadline for IDR rules, Congress determined that regulated parties would have sufficient lead time if the IDR rules were adopted by that date—nearly three full months after the Departments issued the September Rule.

131. In any event, parties did not need months of lead time to prepare for the administrative fee and batching rules. Those rules require relatively little advance notice to implement—

they require paying a fee or grouping claims before submitting them. Parties did not need these rules to be in place any sooner than March or April 2022, when arbitrators would first begin hearing cases. *See supra* ¶ 70. There was ample time for notice and comment.

132. Accordingly, the December 2022 Fee Guidance and the challenged provisions of the September Rule are unlawful and must be set aside because they were issued "without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

COUNT II

THE CHALLENGED PROVISIONS OF THE SEPTEMBER RULE AND THE DECEMBER 2022 FEE GUIDANCE ARE NOT IN ACCORDANCE WITH LAW AND ARE ARBITRARY AND CAPRICIOUS (5 U.S.C. § 706; 42 U.S.C. § 300gg-111)

133. The foregoing paragraphs are incorporated by reference.

134. The sevenfold increase in nonrefundable administrative fees established in the December 2022 Fee Guidance is contrary to the NSA and must be set aside on that basis.

135. The structure and purpose of the NSA make clear that Congress intended the IDR process to be meaningfully available to ensure fair reimbursement of covered claims. Although Congress considered imposing a dollar-value threshold to exclude small-value claims from the IDR process, Congress ultimately rejected such a requirement, choosing instead to make IDR broadly available to all covered claims, regardless of their dollar amount. *See supra* ¶ 39.

136. Further, to ensure that the IDR process would be financially viable for as many claims as possible, Congress authorized batching, *see* 42 U.S.C. § 300gg-111(c)(3)(A), so that providers with small-value claims could aggregate them for purposes of IDR review.

137. Therefore, although the NSA authorizes the Departments to set the IDR administrative fee "in a manner such that the total amount of fees … is estimated to be equal to the"

Departments' expenditures in carrying out the IDR process, *id.* § 300gg-111(c)(8)(B), the Departments are plainly obligated to carry out that process in such a way that administrative fees do not effectively foreclose review for significant numbers of claims.

138. By rendering the IDR process cost-prohibitive for many claims—including the vast majority of claims for certain provider specialties such as radiology—the December 2022 Fee Guidance does not reasonably or permissibly implement the NSA. It is thus "not in accordance with law" and must be set aside. 5 U.S.C. § 706(2)(A).

139. The December 2022 Fee Guidance also must be set aside as arbitrary and capricious because it was not the product of the reasoned decisionmaking the APA requires.

140. The Departments entirely failed to consider a critical aspect of the problem—namely, the effect that a sevenfold increase in the nonrefundable administrative fee would have on healthcare providers' ability to access the IDR process to get paid. With regard to IDR entity fees, the Departments "recogniz[ed] the need to keep the Federal IDR process from being cost-prohibitive for disputing parties." December 2022 Fee Guidance at 6. But the Departments inexplicably ignored that crucial consideration when it came to administrative fees, even though administrative fees present a starker problem because they are nonrefundable even for the prevailing party. Likewise, the Departments failed to consider how the combined effect of the increased administrative fee, together with the increased IDR entity fees, would make IDR cost-prohibitive.

141. The Departments offered no explanation—let alone the reasoned explanation the APA requires—for refusing to address the adverse impact that a nonrefundable $350 administrative fee would have on providers' ability to access IDR. The Departments should have data enabling them to determine precisely how often the amount in controversy exceeds $350. *See* 42

U.S.C. § 300gg-111(c)(7)(B)(iii) (requiring the Departments to publish quarterly reports including, among other information, the dollar amount of the parties' offers); 45 C.F.R. § 149.510(f)(1)(v)(C) (requiring IDR entities to report this information to the Departments). But the Departments did not report or analyze that information. Instead, they simply ignored the devastating impact the fee increase would have on many healthcare providers' ability to access IDR.

142. The Departments further ignored the adverse consequences of making IDR inaccessible. The Departments themselves previously acknowledged that if providers are not "able to resort to the Federal IDR process (and are no longer able to balance bill patients)," they may be "undercompensated for their services," which "could threaten the[ir] viability." 86 Fed. Reg. at 56,044. "This in turn, could lead to participants, beneficiaries and enrollees not receiving needed medical care, undermining the goals of the No Surprises Act." *Id.* Here, however, the Departments said not a word about these harmful consequences, even though their sevenfold increase in the administrative fee creates the very situation about which the Departments were concerned. As a direct result of the Departments' actions, radiologists and other similarly situated physicians "will not be able to resort to the Federal IDR process …, leaving the possibility that they will be undercompensated for their services." *Id.*

143. Nor did the Departments consider how closing off access to IDR will undermine the NSA's goal of reducing the frequency of surprise encounters between patients and out-of-network physicians. If insurers understand that out-of-network physicians cannot use the IDR process to obtain fair reimbursement for their services, insurers have the incentive to terminate their negotiated market-based contracts with in-network providers, forcing more providers out-of-network. It was unreasonable for the Departments to simply ignore how their administrative fee increase exacerbates the very problem Congress aimed to solve in the NSA.

144. The Departments also failed to consider reasonable alternative actions that would allow them to cover their administrative costs without drastically limiting access to IDR. The fee increase appears to have been driven primarily by (1) the Departments' failure to collect administrative fees in the substantial number of cases submitted to IDR that are dismissed as ineligible before the parties submit their offers and (2) the Departments' decision to assist IDR entities with eligibility determinations by devoting the Departments' own resources to pre-eligibility review. But the Departments wholly failed to consider readily available options to address these problems without imposing an exorbitant administrative fee that cuts off access to IDR.

145. For example, the Departments could easily have addressed the collection problem by enforcing their own regulation, which requires the parties to pay the administrative fee at the outset of the proceeding, when the IDR entity is selected, and does not permit them to defer payment until after the eligibility determination is made and the offers are submitted. 45 C.F.R. § 149.510(d)(1)(i). In fact, the Departments' regulation was intended to prevent this very sort of problem. *See* 86 Fed. Reg. at 56,001 (explaining that "it is appropriate that the parties should still be expected to pay the fee" even when a dispute is found to be ineligible).

146. In declining to enforce their regulation as written, the Departments pointed to previous guidance in which they had permitted parties to wait to pay the administrative fee until they submit their offers to the IDR entity. *See supra* ¶ 95. But an agency cannot amend a regulation through subregulatory guidance. The Departments' guidance purporting to change the required time for paying the administrative fee was thus unlawful. And because the December 2022 Fee Guidance is premised on that unlawful guidance, it too is unlawful and must be set aside.

147. The Departments also failed to consider available alternatives that could significantly decrease the number of ineligible disputes submitted to IDR and, correspondingly, the need

for the Departments to expend resources on pre-eligibility review. Much of the problem owes to the fact that insurers often fail to provide information (*e.g.*, the applicable QPA) that only insurers possess and that providers need to determine whether their claims are eligible for IDR. *See supra* ¶¶ 84–86. Nor have the Departments taken any publicly announced actions to penalize insurers for violating their disclosure obligations or to require additional disclosures that could facilitate eligibility determinations. In fact, stakeholders had notified the Departments that they could substantially reduce the number of ineligible disputes (and lower total expenditures) by requiring insurers to use remittance advice remark codes when providing the required disclosures with their initial payment or notice of denial of payment. *See supra* ¶ 87. But the Departments failed to consider that—or any other—alternative to imposing the 600% nonrefundable administrative fee increase.

148. Similarly, the Departments failed to consider apportioning the administrative fee among the parties in ways that could mitigate the access problem. Nothing in the NSA requires the administrative fee to be the same for both parties. The Departments could therefore have imposed an enhanced administrative fee on insurers that fail to furnish providers with the information necessary to determine eligibility. But the Departments did not consider this or any other alternative means of allocating the administrative fee so as to avoid blocking access to IDR.

149. Nor can the Departments justify the December 2022 Fee Guidance by pointing to the possibility of batching. In imposing the $350 fee, the Departments never concluded that batching would prevent the fee from rendering access to IDR cost-prohibitive. They did not address the access problem *at all*. They therefore cannot defend their action on that *post hoc* basis now.

150. The Departments' batching rules also cannot solve the problem with the administrative fees because the batching rules are themselves unlawful, for many of the same reasons. Far

from solving the problem, the Departments' same-service-code batching rule is itself a significant barrier to accessing IDR, with all the attendant adverse consequences already discussed.

151. The Departments' approach to batching is unreasonably restrictive. While the relevant provision of the NSA states that the Departments may broadly permit batching whenever "items and services are *related to the treatment of a similar condition*," 42 U.S.C. § 300gg-111(c)(3)(A)(iii) (emphasis added), the September Rule authorizes batching in a much narrower range of circumstances: only when the "items and services are *the same or similar items and services*," 45 C.F.R. § 149.510(c)(3)(i)(C) (emphasis added).

152. The Departments have thus prohibited batching in a wide range of circumstances where they could have permitted it. For example, although the statute's condition encompasses batching of claims for all of the treatments or procedures in a patient's treatment plan or in that patient's episode of care, the Departments chose instead to restrict batching to claims involving the same or similar item or service. And although the statute's condition encompasses batching of multiple different items and services provided to multiple patients with a similar condition, the Departments chose instead to restrict batching to claims for the same CPT code.

153. Nowhere did the Departments acknowledge that their approach to batching is significantly narrower than what the statute allows. They did not even identify the statutory language permitting them to authorize batching whenever "items and services are related to the treatment of a similar condition." 42 U.S.C. § 300gg-111(c)(3)(A)(iii). Nor did they appear to grasp that their rule would prevent batching in many commonsense circumstances. *See, e.g.*, *supra* ¶ 110. Indeed, the Departments made next to no effort to explain how their approach would work in practice or to grapple with its practical implications for the providers who depend on the IDR process.

154. The Departments also failed to address even a single alternative to their service-code-only batching rule. Despite essentially parroting the statute's other conditions for batching claims, the Departments failed to consider the same approach here: mirroring the statutory text by permitting batching of *all* claims "related to the treatment of a similar condition." 42 U.S.C. § 300gg-111(c)(3)(A)(iii). The Departments also failed to consider any number of other available options, such as allowing batching by episode of care, by American Medical Association service code sections (*e.g.*, 70000 CPT code series, for radiology procedures), and/or by provider sub-specialty.

155. The Departments further failed to reasonably consider whether their "same or similar items or services" criterion served the statutory purposes of batching—"encouraging the efficiency (including minimizing costs) of the IDR process." 42 U.S.C. § 300gg-111(c)(3)(A). A reasonable agency would have asked, for example, whether an approach to batching that is much narrower than permitted by the statute could achieve the efficiencies, cost-savings, and "economies of scale" the Departments themselves recognized that Congress intended. 86 Fed. Reg. at 56,054. Most glaringly, the Departments said nothing at all about whether or how their approach would create sufficient economies of scale to allow physicians, like radiologists, with large numbers of small-value claims to cost-effectively access IDR.

156. The rationales the Departments did give for their batching rule were conclusory. They asserted without explanation that their batching criteria would "avoid combinations of unrelated claims, providers, facilities, … and plans and issuers in a single dispute that could unnecessarily complicate an IDR payment determination and create inefficiencies" in the IDR process. 86 Fed. Reg. at 55,994. And they guessed that their batching criteria *might* "reduce the per-service

cost" of the IDR process by creating "*at least* some economies of scale," while essentially admitting that this was pure speculation, because—having failed to give notice or request comment—they did not know "how prevalent batching will be" or the "potential cost savings." *Id.* at 56,054 (emphasis added). But assertions and guesswork cannot substitute for reasoned explanation.

157. Finally, the Departments claimed that allowing batching only by service code was "likely to reduce redundan[cy]" and "streamline the certified IDR entity's decision-making." *Id.* at 55,994. But the only basis they gave for this belief was rooted in their unlawful "rebuttable presumption" in favor of the QPA. They could not muster another reason why allowing batching exclusively by service code was a rational choice.

158. Accordingly, the challenged provisions are "not in accordance with law" and are "arbitrary, capricious, [and] an abuse of discretion." 5 U.S.C. § 706(2)(A).

PRAYER FOR RELIEF

Plaintiffs respectfully request that the Court enter judgment in their favor and grant the following relief:

A. A declaration that the challenged provisions of the September Rule and the December 2022 Fee Guidance's $350 administrative fee are unlawful.

B. An order vacating the following:

   a. The December 2022 Fee Guidance's $350 administrative fee;

   b. 45 C.F.R. § 149.510(d)(2)(ii); 26 C.F.R. § 54.9816-8T(d)(2)(ii); 29 C.F.R. § 2590.716-8(d)(2)(ii); and

   c. 45 C.F.R. § 149.510(c)(3)(i)(C); 26 C.F.R. § 54.9816-8T(c)(3)(i)(C); 29 C.F.R. § 2590.716-8(c)(3)(i)(C).

C. An injunction barring defendants from enforcing the foregoing provisions;

D. Equitable disgorgement of the administrative fees paid pursuant to the December 2022 Fee Guidance;

E. Attorney's fees and costs pursuant to 28 U.S.C. § 2412; and

F. Any other just and proper relief.

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Respectfully submitted,

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